REMARKS

Claims 18-31 are pending in the application. Claim 18 is in independent form.

The Examiner has objected to the abstract. A responsive change has been made. Also, the specification has been amended to update the reference to a related application and correct a typographical error.

The Examiner has not considered German Patent No. 4,127,550 stating that there is no indication in that the reference was made of record in the parent application serial no. 08/801,240. The Examiner is respectfully referred to the Information Disclosure Statement filed May 4, 1998, reference BN, in the parent application serial no. 08/801,240, which cites German Patent No. 4,127,550. A courtesy copy of German Patent No. 4,127,550 and the English language abstract are enclosed.

The Examiner has rejected claims 18-31 for obviousness-type double patenting over the claims of U.S. Patent No. 6,235,057. A terminal disclaimer overcoming this rejection will be filed when the claims are otherwise held to be allowable.

The Examiner has rejected claims 18-23, 25-27, and 29 under 35 U.S. C. §102(a) as anticipated by French Patent No. 2,704,104 to Hublin, and claims 24, 28, 30, and 31 under 35 U.S.C. §103(a) as obvious over Hublin in view of PCT Application No. 92/03980 to Roger et al.

Applicants enclose declarations of Dr. Roger, Dr. Pinczewski, and Mr. Pflaster, previously submitted in parent application Serial Number 08/801,240, now U.S. Patent No. 6,235,057, showing that the invention of claim 18 was completed in the United States prior to October 28, 1994, the publication date listed on Hublin. Accordingly, applicants respectfully submit that Hublin is unavailable as a reference against the claims.

The Examiner has rejected claims 18-23, 25-27, and 29 under 35 U.S. C. §103(a) as obvious over Japanese Patent No. 5-300917 to Kuriwaka.

Kuriwaka does not describe or suggest a method of attaching a graft of a natural tendon or ligament to bone by inserting a fixation screw device into a bone hole so that the fixation screw device engages the natural tendon or ligament of the graft and presses the natural tendon or ligament of the graft directly and firmly against a sidewall of the bone hole, as recited in claim

18. Indeed, conventional wisdom -- as exemplified by Kuriwaka (a copy of the English translation of which is enclosed) -- has been that screws should not be used to directly secure a natural tendon or ligament graft, because the screw threads would cut the natural tendon or ligament and thereby damage or destroy the graft.

Kuriwaka teaches away from using a screw to directly secure a natural tendon or ligament graft within a bone hole because of the danger of cutting the graft:

> [Problems Resolved by the Invention] However, as Fig. 4 shows, when the tapered screw shaft 54 is screwed into the borehole 52 drilled into the bone 51, the ligament replacement 53 is twisted when it is strongly clasped by the screw threads.
>
> For this reason, ligaments taken from other parts of the body or artificial ligaments cannot be used because they are cut when they are clasped directly. Accordingly, a ligament cut from other parts of the body is used with a small fragment of bone attached to its end and it is the bone fragment which is clasped between the screw shaft 54 and the borehole 52. (Translation at page 5.)

Kuriwaka seeks to overcome these problems by using a two-piece fixation device in which an inner screw shaft 20 is threaded into a tubular body 10 (Fig. 1) to radially expand the body and secure the ligament replacement in the bone hole. In direct contrast to the claimed invention, the screw shaft 20 is not inserted so as to engage the graft and press the graft directly and firmly against a sidewall of the bone hole. Instead, the screw shaft is shielded from the ligament replacement by tubular body 10.

It is true that tubular body 10 has exterior threads which are "chamfered blunt" so as not to "cut or damage the replacement ligament 3" (translation at page 8), and is rotated by an insertion tool to "screw it into the borehole 2" (translation at page 7). But far from inserting the outer tubular body so as to press the ligament replacement directly and firmly against the sidewall of the bone hole -- as claimed by applicants -- Kuriwaka teaches that outer tubular body 10 is to be "screwed into the borehole comparatively lightly" (translation at page 8). The reason for this restriction is clear: despite dulling the threads of outer tubular body 10, Kuriwaka wants to avoid the risk of cutting or otherwise damaging the ligament replacement with the threads if outer tubular body were to tightly engage the ligament replacement as it is screwed in place. It is

only when screw shaft 20 is inserted that the exterior surface of the outer tubular body is pressed "strongly against the interior wall of the borehole 2 and the ligament replacement 3" (translation at page 9). In fact, Kuriwaka is so concerned with damaging the ligament replacement with the threads of outer tubular body 10 that he seeks to prevent body 10 from rotating as shaft 20 is advanced, or allow only slight rotation:

> At this time, if, for example, the tip of a tubular tool (not illustrated) is fitted into the tool fixture 15 of the outer tubular body 10 to restrict ability of the outer tubular body 10 to rotate and another tool (not illustrated) is inserted within that tool to rotate the screw shaft 20, the ligament replacement 3 is not damaged because the outer tubular body 10 does not rotate.
>
> Even if the outer tubular body 10 does rotate slightly, the ligament replacement 3 is not damaged because the threads of the male screw 12 on the outer surface thereof are rounded. (Translation at page 9.)

Therefore, claim 18, and its dependent claims, are patentable over Kuriwaka.

The Examiner has rejected claims 24, 28, 30, and 31 under 35 U.S.C. §103(a) as obvious over Kuriwaka in view of PCT Application No. 92/03980 to Roger et al.

Roger does not overcome the deficiencies in Kuriwaka discussed above. In particular, while Roger discloses a screw for anchoring a graft in a bone hole, the graft includes bony ends which are engaged by the screw. Thus, Roger's screw does not directly engage a natural tendon or ligament of the graft and press the natural tendon or ligament directly and firmly against a sidewall of the bone hole, as recited in claim 18.

Therefore claims 24, 28, 30, and 31 are patentable over Kuriwaka in view of Roger.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a Petition for Extension of Time and the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 29, 2002

Phyllis Kristal

Phyllis K. Kristal
Reg. No. 38,524

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40092919.doc

Version with markings to show changes made

In the Specification:

The paragraph at the beginning of the specification has been amended as follows:

["]This application is a continuation of co-pending application Serial Number 08/801,240 filed on February 19, 1997, now U.S. Patent No. 6,235,057, which is a continuation of application Serial Number 08/614,904 filed on March 13, 1996, now abandoned, which is a continuation of application Serial Number 08/378,246 filed on January 24, 1995, now abandoned.

In the Claims:

Claim 30 has been amended as follows:

30. (Amended) [A] The method of claim 18 for the reconstruction of an anterior cruciate ligament of [a] the patient, [comprising the steps of:] wherein forming the hole includes

[a)] forming [a] the hole in a femur from a suitable point in an intercondylar notch in said femur anteriorly and laterally; and

[b) disposing at least a portion of a graft of a natural tendon or ligament in said hole; and

c) inserting a fixation screw device into said hole so that the fixation screw device engages the natural tendon or ligament of the graft and presses] the natural tendon or ligament of the graft is pressed directly and firmly against [a] the sidewall of said hole in said femur, the fixation screw device being cannulated and having a screw thread which is devoid of an outermost cutting line and is substantially nontapered, the fixation screw device having a hemispherical head at an end thereof.

In the Abstract:

The abstract of the disclosure has been amended as follows:

A method for the reconstruction of the anterior cruciate ligament of a patient is described. The process comprises the steps of:

1) harvesting from the patient semitendonosus and gracilis tendons, or other suitable tendons of adequate length, to form a tendon graft;

2) forming a hole through the patient's femur from the intercondylar notch therein anteriorly and laterally;

3) enlarging the cross-sectional area of that femoral hole adjacent the notch sufficiently to receive one end of the tendon graft and a suitable screw;

4) forming a suitably positioned hole through the patient's tibia opening at one end adjacent the medial tibial spine and having a cross-sectional area sufficient to receive the other end of the tendon graft and a suitable screw;

5) drawing the one end of the tendon graft through the tibial hole and the joint into the femoral hole while leaving the other end of the tendon graft [is] in the tibial hole;

6) inserting a suitable screw into the femoral hole from its intercondylar notch end until the head of the screw is just within that end of the hole and the screw is pressing the tendon graft directly and firmly against a sidewall of the femoral hole; and

7) after tensioning the tendon graft, inserting a suitable screw into the hole in the tibia externally until the head of the screw is within the exterior end of the tibial hole and the screw is pressing the tendon graft directly and firmly against a sidewall of the tibial hole.

PATENT
ATTORNEY DOCKET NO. 0231-0187
00167/311001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gregory J. Roger et al. Art Unit: 3738
Serial No.: 08/801,240 Examiner: D. Willse
Filed : February 19, 1997
Title : METHOD FOR SOFT TISSUE RECONSTRUCTION

Reviewed
7-15-02

Box AF
Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION UNDER 37 C.F.R. §1.131

We, Gregory J. Roger and Leo A. Pinczewski, declare as follows:

1. We are citizens of Australia.

2. We are the inventors of the subject matter claimed in the above-identified patent application.

3. Prior to October 28, 1994, we conceived in Australia fixation screw devices for attaching a graft of soft material consisting of a tendon or ligament or an artificial tendon or ligament within a hole in the bone of the patient by engaging the soft material of the graft and pressing the soft material of the graft directly and firmly against a sidewall of the bone hole, and we had such fixation screw devices (which we called the "RCI screw") made in Australia.

4. Prior to October 28, 1994, we brought specimens of the fixation screw devices described in Paragraph 3 above to

Date of Deposit November 20, 1998
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Laura C. Mumy

Smith & Nephew DonJoy, Inc. in San Diego, California ("DonJoy"), for the purpose of testing the fixation screw devices.

5. Prior to October 28, 1994, we performed tests on four specimens of the fixation screw device described in Paragraph 3 above on cadaver knee specimens in a laboratory at DonJoy, in the presence of Mr. Daniel Pflaster, a DonJoy employee. During each test, while Dr. Roger observed, Dr. Pinczewski inserted a specimen fixation screw device into a hole in either the femur or the tibia of the cadaver to secure a natural tendon graft without boney ends within the hole (the graft had been harvested from the cadaver) by engaging the soft material of the graft and pressing the soft material of the graft directly and firmly against a sidewall of the hole. At our direction and in our presence, Mr. Pflaster tested the strength of the attachment by applying a loading force to the graft in line with the hole, measuring the load required to pull the graft out of the hole, and recording the measurements on a "test data recording form." A copy of the test data recording form, with the date redacted, is attached as Exhibit A (the test data are explained in an accompanying declaration by Mr. Pflaster).

6. These tests showed that the tested specimens of the fixation screw device withstood large pull-out loads (up to 71.8 lbs., on average), and therefore demonstrated to our satisfaction that the engagement of the fixation screw device against the soft tissue of the tendon securely holds the tendon in the bone hole. The test results were summarized in an entry in Dr. Roger's diary for the RCI screw project dated prior to October 28, 1994:

"[D]id four tests in the Lab at DonJoy which show that the interference fit of the RCI screw will hold tendon alone."

The diary entry, with the date and other entries in the diary redacted, is attached as Exhibit B.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Gregory J. Roger

Date: 16th November, 1998

Leo A. Pinczewski

Date: 16th November, 1998

339042.B11

SMITH & NEPHEW DONJOY PROPRIETARY INFORMATION

BLOCK #: 2 TEST ID: PINCZEWSKI - HAMSTRING

RANGE CARTRIDGES:	DISP: ±5 in	LOAD: ±150 lbs		
SCALE FACTORS:	LEVEL: 100	TIME: 1.0	RETURN RATE: 100	
SEGMENT PARAMETERS:	SEGMENT # 1	RATE: 20% (1 in/s)	LEVEL: 100% (5 in)	TIME/FREQ:
	2	100%	0	

SPECIMEN:	FILE:		
1	LEO1	65.8	
1	LEO2	80.0	
✓ 1	LEO3	79.0	
✓ 2	LEO4	99.2 LIGATURE TENDON NOT MOVE PROPERLY AT START OF TEST	→ 2
2	LEO5	47.2	RETEST REMAINING TENDON
✓ 3	LEO6	83.4	
✓ 4	LEO7	75.6	
	sp1	79.0	
	sp2	99.2	
	sp3	83.4	
	sp4	75.6	
	AVG (n=4)	71.8 lbs	
	S.D. (n=4)	13.3	

COMMENTS:

FEMUR - TENDON FAILED MIDSUBSTANCE
@ CRYOCLAMP (FREEZE/TIBIA INTERFACE)
- TENDON SLIPPED (FROZEN) OUT OF CLAMP.
- PULL OUT OF TUNNEL; NO SUTURES CAME OUT MID-ITIBECTANCE TEAR

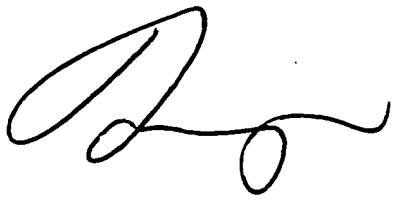
FEMUR - ONE (OF 2) TENDONS PULL OUT OF TUNNEL (OTHER OUT OF CLAMP)
RETEST REMAINING TENDON - PULLED OUT OF FEMORAL HOLE WITH ITS SUTURES.

TIBIA - 2 TENDON FAILED MIDSUBSTANCE
PROBABLY AT END OF SCREW TIP IN TIBIA.

TIBIA - 2 TENDONS PULL OUT TUNNEL WITH SUTURES.
(NO SCREWS MIGRATED) OBVIOUSLY ALTHOUGH
NOT EXAMINED FOR AT THIS TEST.

EXHIBIT A

EXHIBIT B



Went to San Diego and gave good talk. Then did four tests in the Lab at Donjoy which show that the interference fit of the RCI screw will hold tendon alone. Very exciting stuff. Operated in Norwich, Oulu, Florence and they all went well. Also spoke to the sales staff at Hamburg. Exhausting trip but it went well. Now the next generation.

PATENT
ATTORNEY DOCKET NO. 0231-0187
00167/311001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

reviewed DM 1-15-02

Applicant : Gregory J. Roger et al. Art Unit: 3738
Serial No.: 08/801,240 Examiner: D. Willse
Filed : February 19, 1997
Title : METHOD FOR SOFT TISSUE RECONSTRUCTION

Box AF

Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION UNDER 37 C.F.R. §1.131

I, Daniel Pflaster, declare as follows:

1. I am an employee of the Bracing and Support Systems Division of Smith & Nephew Inc. in Vista, California, formerly Smith & Nephew DonJoy, Inc. of San Diego, California ("DonJoy"). On information and belief, Smith & Nephew Inc. is the assignee of the above-identified patent application.

2. Since prior to October 28, 1994, I have worked in the research area at DonJoy, and one of my responsibilities has been to evaluate techniques for attaching soft tissue to bone.

3. Prior to October 28, 1994, Gregory Roger and Leo Pinczewski visited DonJoy to test a fixation screw device for attaching a graft of soft material consisting of a tendon or ligament or an artificial tendon or ligament within a hole in the bone of the patient by engaging the soft material of the graft and pressing the soft material of the graft directly and firmly against a sidewall of the bone hole.

Date of Deposit November 20, 1998
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Laura A Munson

4. Prior to October 28, 1994, I was present when Dr. Roger and Dr. Pinczewski performed tests on four specimens of the fixation screw device described in Paragraph 3 above on cadaver knee specimens in a laboratory at DonJoy. During each test, while Dr. Roger observed, Dr. Pinczewski inserted a specimen fixation screw device into a hole in either the femur or the tibia of the cadaver to secure a natural tendon graft without boney ends within the hole (the graft had been harvested from the cadaver) by engaging the soft material of the graft and pressing the soft material of the graft directly and firmly against a sidewall of the hole. At the direction of Dr. Roger and Dr. Pinczewski, I tested the attachment strength by applying a loading force to the graft, in line with the hole, and measured the load required to pull the graft out of the hole. I recorded the measurements on a "test data recording form," a copy of which is attached as Exhibit A (with the date redacted).

5. The data shown on the test data recording form of Exhibit A reflect the results of, and my comments on, seven tests performed using the four specimens of the fixation screw devices. Three tests (labelled "Leo1," "Leo2", and "Leo3" on the form) were performed using specimen #1. In the first two tests, either the soft tissue or the equipment that I used failed. In the third test ("Leo3"), a load force of 79 lbs. was required to pull out the soft tissue (i.e., overcome the attachment provided by the fixation screw device). The tests using specimen #2 ("Leo4" and "Leo5"), specimen #3 ("Leo6"), and specimen #4 ("Leo7") showed that load forces of 49.2 lbs., 83 lbs., and 75.6 lbs.,

respectively, were required to pull out the tissue against the holding forces provided by the specimens. These loads are listed in the third column from the left on the form, together with the average pull-out force of 71.8 lbs.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Daniel Pflaster

Date: 11/10/98

339042.B11

SMITH & NEPHEW DONJOY BIOMECHANICS RESEARCH LAB

BLOCK #: 2 TEST ID: PINCZEWSKI - HAMSTRING

RANGE CARTRIDGES:	DISP: ±5 in	LOAD: ±150 lbs			
SCALE FACTORS:	LEVEL: 100	TIME: 1.0	RETURN RATE: 100		
SEGMENT PARAMETERS:	SEGMENT #: 1	RATE: 20% (1 in/s)	LEVEL: 100% (5 in)	TIME/FREQ:	
	2	100%	0		

SPECIMEN:	FILE:						COMMENTS:
1	LEO1	65.8					FEMUR - TENDON FAILED MIDSUBSTANCE @ CRYOCLAMP (FREEZE/TOHN INTERFACE) - TENDON SLIPPED (FROZEN) OUT OF CLAMP - PULL OUT OF TUNNEL, NO SUTURES CAME OF MID-SUBSTANCE TE
1	LEO2	30.0					
✓ 1	LEO3	79.0					
✓ 2	LEO4	44.2	LARGER TENDON NOT IN HOLE PROPERLY AT START OF TEST			→ 2	FEMUR - ONE (OF 2) TENDONS PULL OUT OF TUNNEL (FEMUR OUT OF CLAMP)
2	LEO5	47.2				RETEST REMAINING TENDON	- PULLED OUT OF FEMORAL HOLE WITH (1) SUTURE
✓ 3	LEO6	83.4					TIBIA - 2 TENDON FAILED MIDSUBSTANCE
✓ 4	LEO7	75.6					PROBABLY AT END OF SCRGW TIP IN TIBIA.
							TIBIA - 2 TENDONS PULL OUT TUNNEL WITH SUTURES.
							(NO SCRGWS MIGRATED OBVIOUSLY ALTHOUGH NOT EXAMINED FOR AT THIS TIME)
	SP1	79.0					
	SP2	44.2					
	SP3	83.4					
	SP4	75.6					
	AVG (n=4)	71.8 lbs					
	S.D. (n=4)	13.3					